PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/696,044			
Filing Date	October 29, 2003			
First Named Inventor	Robert M. Noack et al.			
Art Unit	Not Yet Known			
Examiner Name	Not Yet Known			
Attorney Docket Number	00903/1/US			

				DOCUMENTS		
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
/MY/		US- 3,885,026	05/20/75	H. Heinemann et al.		
/MY/		US- 4,096,238	06/20/78	A. Zaffaroni et al.		
/MY/	-	US- 4,134,943	01/16/79	K. Knitsch et al.		
		US- 4,244,941	01/13/81	C. Lerk		
		<sup>US-</sup> 4,687,660	08/18/87	R. Baker et al.		
		<sup>US-</sup> 4,837,030	06/06/89	J. Valorose et al.		
		<sup>US-</sup> 4,871,549	10/03/89	Y. Ueda et al.		
		us- 4,880,631	11/14/89	J. Haslam et al.		
		us- 4,892,742	01/09/90	N. Shah		
		us- 4,919,938	04/24/90	C. Lovegrove et al.		
		<sup>US-</sup> 4,946,686	08/07/90	G. McClelland et al.		
		US- 4,994,273	02/19/91	G. Zentner et al.		
		US- 5,055,306	10/08/91	B. Barry et al.		
		US- 5,102,665	04/07/92	A. Schaeffer		
		US- 5,175,003	12/29/92	R. Goldman		
		us- 5,260,069	11/09/93	C. Chen		
V		US- 5,356,467	10/18/94	B. Oshlack		
•		US- 5,458,887	10/17/95	C. Chen et al.		
/MY/		US- 5,505,966	04/09/96	P. Edman et al.		

		FORE	IGN PATENT DOC	UMENTS		
	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
			MM-DD-YYYY		Or Relevant Figures Appear	٢
/MY/	WO 90/01926	03/08/90	Himedics, Inc.		l_	
1		WO 93/00889	01/21/93	L.C. Phar-Chem LTD.		
		WO 94/22431	10/13/94	Kabi Pharmacia AB		
$\sqrt{I}$		WO 97/25979	07/24/97	Perio Products LTD	-	
_		WO 98/03161	01/29/98	Dexcel LTD		L
/MY/		WO 98/15265	04/16/98	Danbiosyst UK Limited		

		·	
Examiner Signature	/Micah Paul Young/	Date Considered	03/17/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of Information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449/PTO Application Number 10/696,044 October 29, 2003 Filing Date INFORMATION DISCLOSURE First Named Inventor Robert M. Noack et al. STATEMENT BY APPLICANT Art Unit Not Yet Known (Use as many sheets as necessary) **Examiner Name** Not Yet Known Sheet 2 00903/1/US 01 4 Attorney Docket Number

				DOCUMENTS	
Examiner Cite Document Number Initials* No.1		Document Number  Number-Kind Code <sup>2 (F known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/MY/		US- 5,520,931	05/28/96	C. Persson et al.	
		<sup>US-</sup> 5,607,685	03/04/97	M. Cimbollek et al.	
		us- 5,609,884	03/11/97	S. Desai	
		US- 5,656,294	08/12/97	D. Friend et al	
		US- 5,656,296	08/12/97	S. Khan et al.	
		US- 5,670,170	09/23/97	F. Grimmett et al.	
		<sup>US-</sup> 5,711,967	01/27/98	R. Juch	
		US- 5,840,332	11/24/98	E. Lerner et al.	
		US- 5,881,388	03/16/99	K. Pratt et al	
		US- 5,900,252	05/04/99	M. Calanchi et al.	
		US- 6,004,581	12/21/99	S. Jepsen et al.	
		US- 6,068,856	05/30/00	G. Sachs et al.	
		<sup>US-</sup> 6,068,859	05/30/00	W. Curatolo et al.	
		US- 6,074,669	06/13/00	V. Nagaprasad et al.	
		US- 6,150,410	11/21/00	K. Engh et al.	
		us- 6,228,398	05/08/01	J. Devane et al.	
V		US- 6,231,888	05/15/01	E. Lerner et al.	
		<sup>US-</sup> 6,287,599	08/11/01	B. Burnside et al.	
/MY/		US- 6,312,728	11/06/01	E. Beiman et al.	

		FORE	IGN PATENT DOC	JMENTS		
Examiner Cite No.1		Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>8</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T <sup>6</sup>
		WO 98/22095	05/28/98	Procter & Gamble Co.		
		WO 98/26767	06/25/98	Poli Industria Chimica S.P.A.		
		WO 99/00136	01/07/99	J. Rowe		
1/		WO 99/66904	12/29/99	Theratech Inc.		
V		WO 00/25757	05/11/00	Merck & Co., Inc.	-	
/MY	$T^{-}$	WO 00/69420	11/23/00	Coraltis Ltd.		

Examiner		Date	03/17/2007
Signature	/Micah Paul Young/	Considered	03/11/2001

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 3

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/696,044			
Filing Date	October 29, 2003			
First Named Inventor	Robert M. Noack et al.			
Art Unit	Not Yet Known			
Examiner Name	Not Yet Known			
Attorney Docket Number	00903/1/US			

Examiner	Cite No.1	Document Number	U. S. PATENT D	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials*	No.'	Number-Kind Code <sup>2 (# known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-			
		US-	<del> </del>		
,	· · · · ·	US-			
		US-	-		
		US-			
		US-		······································	
		US-	†		
•		US-		· · · · · · · · · · · · · · · · · · ·	
		US-			
· · · ·		US-			
_		US-			
		US-	<del> </del>		<del> </del>
		US-	+ +		<u> </u>

			IGN PATENT DOC			
Initials*	Cite No.1	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	
	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	Т	
/MY	1	WO 01/05430 A1	01/25/01	Merck & Co., Inc.		Π
. 1 .		WO 01/45706	06/28/01	Pharmacia Corporation		Γ
V		EP 0 310 814	10/06/87	American Cyanamid Co.		Π
		EP 0 365 947 B1	05/02/90	DIB Limited		
/MY/		EP 0 572 942	12/08/93	Monsanto Italiana S.p.A.	,	

Examiner Signature	/Micah Paul Young/	Date Considered	03/17/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Substitu	Substitute for form 1449/PTO			Complete if Known	1	
				Application Number	10/696,044	
INFORMATION DISCLOSURE			CLOSURE	Filing Date	October 29, 2003	
STA	STATEMENT BY APPLICANT		First Named Inventor	Robert M. Noack et al.		
				Art Unit	Not Yet Known	
	(Use as many sheets as necessary)		Examiner Name			
Sheet	4	of	4	Attorney Docket Number	00903/1/US	

Examiner Cite No.1		NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
/MY/		LEE F. SIEW, ABDUL W. BASIT, AND J. MICHAEL NEWTON, "The Potential of Organic-Based Amylose-Ethylcellulose Film Coatings as Oral Colon-Specific Drug Delivery Systems", AAAPS PharmSciTech, 2000, 9 pages, 1 (3), article 22, The School of Pharmacy, London, UK		
		SURELEASE, Product Information, Product Specification, Formula No. E-7-19010, (2001), Colorcon, 2 pages		
		SURELEASE, Technical Data; Coating Application, (2001), Colorcon, 2 pages		
		SURETERIC, Product information; Product Data Sheet; Formula: YAE-6-18107, (2000), Colorcon, 2 pages		
		BILL ST. JOHN, "Controlled Delivery Oral Dosage Forms in the New Millennium", Pharmaceutical Manufacturing and Packing Sourcer, © 2000, 4 pages, Ballantyne Ross Ltd International Media, London, UK		
		ZEIN, 3 pages, downloaded from internet at www.freeman@lanline.com on 9/6/2002, Freeman Industries LLC, (last modified 6/13/2002)		
		ACRYL-EZE, Technical Data Sheet; Enteric Coating Stability, (2001), Colorcon, 2 pages		
$\Psi$		SURETERIC, Information sheet, Preparation & Use Guidelines; © 2001 Colorcon, 2 pages		
/MY/		FUKUI ET AL., "Preparation of enteric coated timed-release press-coated tablets and evaluation of their function by in vitro and in vivo test for colon targeting", Int. J. of Pharm., 19 May 2000, pages 7-15, vol. 204	,	

Examiner	/Micah Paul Young/	Date	
	/Micah Paul Young/	Date	03/17/2007
Signature	·	Considered	00/1//2007

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.